DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

DEC 29 1999

1589 '00 JAN -4 P1:54

The Honorable Asa Hutchinson
Member, U.S. House of Representatives
United States Federal Building
Harrison, Arkansas 72601

Dear Mr. Hutchinson:

Thank you for your letter of November 12, 1999, on behalf of your constituent, Mr. Mike Seals of Greenwood, Arkansas, regarding ephedrine. Mr. Seals believes this substance should have strong controls placed on it. We thank you for forwarding your constituent's concerns to the Food and Drug Administration (FDA or the Agency).

As background, ephedrine alkaloids are amphetamine-like compounds with potentially strong stimulant effects on the cardiovascular (heart and blood vessels) and nervous systems. The ephedrine alkaloids in dietary supplements are naturally occurring stimulants and usually are derived from one of several species of herbs of the genus Ephedra, sometimes called Ma huang or Chinese Ephedra.

On June 4, 1997, FDA published a proposed rule in the Federal Register (FR) regarding the formulation and labeling of dietary supplements containing ephedrine alkaloids. In the proposed rule, the Agency is proposing:

- to make a finding, which will have the force and effect of law, that a dietary supplement is adulterated if it contains 8 milligrams (mg) or more of ephedrine alkaloids per serving, or if its labeling suggests or recommends conditions of use that would result in intake of 8 mg or more in a six-hour period or a total daily intake of 24 mg or more of ephedrine alkaloids;

- to require that the label of dietary supplements that contain ephedrine alkaloids state, "Do not use this product for more than 7 days";

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- to prohibit the use of ephedrine alkaloids with ingredients, or with ingredients that contain substances, that have a known stimulant effect (e.g., sources of caffeine or yohimbine), which may interact with ephedrine alkaloids;

- to prohibit labeling claims that require long-term intake to achieve the purported effect (e.g., weight loss and body building);

- to require a statement in conjunction with claims that encourage short-term excessive intake to enhance the purported effect (e.g., energy) that, "Taking more than the recommended serving may result in heart attack, stroke, seizure or death"; and

- to require specific warning statements to appear on product labels.

The proposal also articulates FDA's policy that products marketed as alternatives to illicit street drugs are drugs, not dietary supplements.

FDA proposed this rule in response to serious illnesses and injuries associated with the use of dietary supplement products, which contain ephedrine alkaloids and in response to the Agency's investigations and analyses of these illnesses and injuries. Reported adverse events range from episodes of high blood pressure, irregularities in heart rate, insomnia, nervousness, tremors, and headaches, to seizures, strokes, and death.

As of January 1997, FDA had received over 800 reports of adverse events associated with the use of more than 100 different dietary supplement products which contained, or were suspected of containing, ephedrine alkaloids. The adverse events reports showed consistent patterns of illness and injury among otherwise healthy individuals and those with underlying diseases or conditions. FDA continues to receive additional reports of adverse events associated with the use of these products.

The proposed measures were developed based on FDA's review of its adverse event reports, the scientific literature, and public comments reviewed by the Agency, including comments generated by an October 1995, advisory working group public meeting and an August 1996, public meeting of FDA's Food

Advisory Committee. These experts suggested a number of steps the Agency might take to reduce injuries associated with the use of dietary supplements containing ephedrine alkaloids. If implemented, the proposed rule will reduce the risk of adverse events for consumers who use these products.

FDA invited written comments on the proposal from the public and industry. There was an initial 75-day comment period on the proposed rule. On September 18, 1997 (62 FR 48968), that comment period was reopened for an additional 75 days until December 2, 1997. Your comments have been forwarded to the Administrative Docket for this issue. While the Agency is under no legal obligation to consider comments received after the comment period has closed, we try to accommodate all comments as time and resources permit. The Agency is considering comments, data, and other information it has received in developing a final rule.

We trust this information responds to your concerns. If we may be of any further assistance, please contact us again.

Sincerely,

Kristina Harper

for Melinda K. Plaisier
Associate Commissioner
for Legislation

cc: Dockets Management Branch
(Docket #95N-0304)

ASA HUTCHINSON
3D DISTRICT, ARKANSAS

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November 12, 1999

Diane Thompson
Associate Commissioner for Legislative Affairs
Food and Drug Administration
U.S. Department of Health and Human Services
Parklawn Building
5600 Fishers Lane, Room 15-55
Rockville, Maryland 20857

Dear Ms. Thompson:

Enclosed you will find a copy of the letter I received from my constituent Mike Seals, 908 West Baltimore Street, Greenwood, Arkansas 72936, concerning Ephedrine.

According to Mr. Seals, Ephedrine is addictive and it should be under the control of the Food and Drug Administration.

I would appreciate your looking into this matter and providing a written response to my Harrison office.

Thank you in advance for your assistance.

Sincerely,

Asa Hutchinson
Member of Congress

AH:sh
Enclosure

99-7233

Hutchinson, Asa

From: steviedearborn@yahoo.com[SMTP:steviedearborn@yahoo.com]
Sent: Monday, October 25, 1999 8:21 PM
To: Hutchinson, Asa
Subject: drugs

FROM:

NAME: mike seals
ADDRESS: 908 west baltimore ST
greenwood, AR 72936

Representative Hutchinson:

congressman Hutchinson,I have a problem with a drug called Ephedrine.I believe it is available in any convenience store in Arkansas.Please allow me to make it clear that I have never used any illegal drug,however I do have a problem with this drug and I need help.I also believe this drug should have strong controls placed upon it for several diffrent reasons.I am aware that you are very busy at this time,but I would greatly appreciate it if you would contact me as soon as possible.If this drug could be controlled Ibelieve it could reduced the manufacture of crystal meth as well as the abuse of this drug by it self.Thank you for your time.Mike seals 501-996 2850.